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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,930	11/30/2001	Jane Hirsh	CP 104	2912

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,930	HIRSH ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Extension of Time and Amendment filed 05/28/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al. US 6,294,199.

Conley teaches method of treating a bacterial infection comprising administering composition comprises amoxycillin (see abstract). The composition can be a modified release dosage formulation comprises an immediate release phase and a slow release phase (column 9, lines 5-58). The modified release dosage form can be a dispersible tablet, a swallow tablet, a chewable tablet that may also be effervescent, a capsule or a sachet (column 9, lines 66 through column 10, lines 1-3). The modified release tablet can be formulated in a bi-layered tablet comprises an immediate release layer which comprises amoxycillin, disintegrants, compression aids, diluents, lubricants, and the like, which will disintegrate rapidly; and a slow release layer which comprises amoxycillin together with release retarding polymers (columns 11-12). Columns 15-17 disclose the process of making the composition.

Conley is silent as to the teaching that the immediate release layer dissolved intraorally. However, Conley teaches the modified release formulation that can be formulated in a chewable tablet. Thus, such language does suggest the active agent in the immediate release layer disintegrates rapidly in the mouth, and therefore, provide intraoral absorption. Accordingly, it would have been *prima facie* obvious for one of ordinary skill in this art to optimize Conley's modified release formulation with the expectation of at least similar result, because Conley teaches the advantageous result in the use of bi-layer chewable/effervescent tablet comprising active agent in both, the immediate release layer, and the delay/slow release layer.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al.

Conley is relied upon for the reason stated above. The reference is silent as to the method of administering the modified release formulation as claimed in claim 21. However, Conley teaches a bi-layer chewable tablet that comprises an immediate release layer that will disintegrate rapidly; and a slow release layer which after oral ingestion will disintegrate/dissolve in the intestine (columns 11-12). Thus, it is the position of the examiner that such language does suggests that after the effervescent of the immediate release layer in the mouth, the ingestion of the slow release layer then occurs. Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable administration method with the expectation of at least similar result, because Conley teaches a modify release

formulation having biphasic release profile that fall within the claimed range (column 9, lines 28-44).

Response to Arguments

Applicant's arguments filed 05/28/03 have been fully considered but they are not persuasive.

Applicant argues that the amoxycillin taught by Conley is not a candidate for intraoral administration due to its large dose, large molecular weight, and low solubility in water. Thus, Conley does not teach a pharmaceutical composition for intraoral administration. Contrary to the applicant's argument, it is noted that the features upon which applicant relies (i.e., the criteria for a drug to be administered intraorally, such as, molecular weight smaller than 350, small dose, and solubility in water) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Conley teaches the dosage form suitable for chewing. Thus, such language does suggest that the active ingredient, when chew would exhibit some absorption through the oral mucosal. The generic term "active ingredient capable of intraoral administration" in the claims permits the use of amoxycillin taught by Conley, since Conley specifically teaches that the active ingredient can be incorporated into a chewable dosage form.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600